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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,339 03/29/2001		Sara Fuchs	FUCHS=2A	3100
1444	7590 09/30/2002			
	AND NEIMARK, P.L.L.	EXAMINER		
624 NINTH S SUITE 300	·	HAYES, ROBERT CLINTON		
WASHINGT	ON, DC 20001-5303		ART UNIT	PAPER NUMBER
			1647	
		,	DATE MAILED: 09/30/2002	\mathcal{G}^{\perp}

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Office Action Summary Summary Summary Summary								
## Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS SCIENCE AND SAY OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS ACTION IS PROVED SAY. A THE REPLY OF THIS SET OF THIS SET OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS SET OF THIS SET OF THE MAILING DATE OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS SET OF THIS SET OF THIS SET OF THIS SET OF THE MAILING DATE OF THE MAILING DATE OF THIS SET OF THIS SET OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS SET OF THIS SET OF THIS SET OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THIS SET OF THE MAILING DATE OF THE MAILING DATE OF THI	•			Application No.	Applicant(s)			
Robert Hayes	,			09/820,339	FUCHS ET AL.			
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of them may be available under the growing of ST CFR 1.13(g). In no event, however, may a reply be timely fited if the period for reply appellad above is less than firity (30) days, a reply within the statutory minimum of thirty (30) days will be considered limity). If No period for reply appellad above is less than firity (30) days, a reply within the statutory minimum of their (40) MONTH of the period for reply appellad above, the maximum statutory period will apply and will expire (8) (MONTH'S from the making date of this communication. Fallwels to reply within the set of extended period for reply will, by statutic cause the application to become ARANDONED (65 U.S. 6 ± 133). Period of the set of the set of the communication, even if findly fleet, may reduce any earned patient term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filled on 21 December 2001. 1) This action is FINAL. 2) This action is ron-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 7) Claim(s) is/are rejected. 7) Claim(s) is/are subjected to by the Examiner. 4) The drawing(s) filed on is/are: a) cocepted or b) believe the Examiner. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) cocepted or bin office action. 11) The proposed drawings are required in reply to this Office action. 12) The coth or declaration is objected to by the Examiner. 13 proposed, corrected drawings are required in reply to this Office action. 14 proposed drawings are required in reply to	Period fo	The MAILING DATE of or Reply	this communication app	ears on the cover she t with the c	orrespondence address			
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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7 and 20, drawn to a polypeptide capable of modulating the autoimmune response of an individual to acetylcholine receptor and pharmaceutical compositions comprising the same, classified in class 514, subclass 2, for example.
 - II. Claims 8-19, drawn to a method of producing a polypeptide comprising a DNA molecule, vectors, and cells comprising the same, classified in class 435, subclass 69.1, for example.
 - III. Claim 21, drawn to a method for alleviating and/or treating myasthenia gravis, comprising administering to an individual in need thereof an effective amount of a polypeptide, classified in class 514, subclass 2, for example.
 - IV. Claim 22, drawn to a method for diagnosing myasthenia gravis comprising determining anti-AchR antibody titer, classified in class 435, subclass 7.1, for example.
- 2. The inventions are distinct, each from the other because of the following reasons:
- 3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, III, and IV are directed to methods that are distinct both

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physically and functionally, and are not required one for the other. Invention II requires search and consideration of producing a polypeptide, which is not required by any of the other Inventions. Invention III requires search and consideration of alleviating and/or treating myasthenia gravis, which is not required by any of the other Inventions. Invention IV requires search and consideration of diagnosing myasthenia gravis comprising determining anti-AchR antibody titer, which is not required by any of the other Inventions.

- 4. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention I could be made by materially different processes such as chemical synthesis or isolation and purification from natural sources.
- 5. Inventions I and each of III and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention I can be used to isolate receptors.
- 6. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

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A. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 1.

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- B. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 2.
- C. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 5.
- D. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 6.
- E. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 7.
- F. Claims 1-22, each in part, as the inventions pertain to SEQ ID NO: 8.
- 7. The inventions are distinct, each from the other because of the following reasons:
- 8. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A, B, C, D, E, and F are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention A requires search and consideration of SEQ ID NO: 1, which is not required by any of the other Inventions. Invention B requires search and consideration of SEQ ID NO: 2, which is not required by any of the other Inventions. Invention D requires search and consideration of SEQ ID NO: 5, which is not required by any of the other Inventions. Invention D requires search and consideration of SEQ ID NO: 6, which is not required by any of the other Inventions. Invention E requires search and consideration of SEQ ID NO: 7, which is not required by any of the other Inventions. Invention F requires search and consideration of SEQ ID NO: 8, which is not required by any of the other Inventions. Each sequence requires a separate search of the literature

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and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

- 9. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-IV. In order to be fully responsive, Applicant must elect one group from I-IV and one group from A-F.
- 10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.
- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Hayes whose telephone number is 703-305-3132. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN September 27, 2002 SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600